

Phillip Wm. Lear
Lear & Lear PLLC
808 E South Temple Street
Salt Lake City, UT 84102
Telephone: (801) 538-5000
Facsimile: (801) 538-5001
Email: phillip.lear@learlaw.com
Local Attorney for Linda P. Smith

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH
CENTRAL DIVISION

LINDA P. SMITH,

Plaintiff

Case No. 1:21-cv-00047-HCN-DBP

v.

XAVIER BECERRA, in his capacity
as the Secretary of the United States
Department of Health and Human
Services,

Defendant

LINDA SMITH'S MOTION TO
ALTER OR AMEND JUDGMENT

JURY TRIAL DEMANDED

Judge Howard Nielson, Jr.
Magistrate Judge Dustin B. Pead

Pursuant to FED.R.CIV.P. 59(a)(2)/(e) and in an effort to avoid unnecessary appellate practice, Plaintiff Linda Smith respectfully files this motion to alter or amend the judgment entered January 19, 2022. That judgment, apparently, was premised on the idea that the Secretary's offer to pay the three claims that formed the genesis of this suit (while continuing to deny the allegations of the Complaint) rendered the rest of the case moot. *See* Dkt. #52. That is simply not true. In essence, the Court's judgment imposed a rejected settlement offer that was designed to avoid a judicial decision on any of the legal issues so that the Secretary may continue to enforce a bad faith,¹ illegal policy and also continue to subject Medicare insureds to repeated litigation.

This is a case about a bad faith, illegal policy that is being used to improperly deny coverage of CGM devices that save people's lives. Currently, the Secretary is using this policy to illegally deny ~13,000 CGM claims each month. As published on December 28, 2021, the Secretary plans to continue this bad faith, illegal conduct for another year. Indeed, the Secretary is continuing to apply the bad faith, illegal conduct *to Mrs. Smith*. This case is not moot.

Accordingly, Plaintiff respectfully requests that the judgment be withdrawn, that the Court set aside CMS 1682-R as issued in violation of 42 U.S.C. § 1395hh

¹ Mrs. Smith does not use that phrase lightly. Nevertheless, the Secretary's conduct in this regard has been adjudicated to constitute "bad faith." *See Olsen v. Becerra*, 2021 WL 3683360 (E.D. Wash. April 20, 2021).

(and enjoin its continued enforcement), address the other claims for relief, and enter a new judgment in Mrs. Smith’s favor.

Previously, this Court considered having a hearing on the pending motions for summary judgment in late February 2022. Respectfully, Mrs. Smith suggests that the Court go forward with that hearing date and take up the present motion as well as the previously pending motions for summary judgment at that time.

BACKGROUND

Factual Background

At the outset, it is important to understand that Medicare Part B (the portion of Medicare relevant here) is a “voluntary insurance program.” *See* 42 U.S.C. §§ 1395j (“voluntary insurance program”) and 1395k. Just like Aetna and Humana, Medicare Part B insureds (like Mrs. Smith) pay monthly premiums in exchange for coverage of qualifying claims. *See* 42 U.S.C. §§ 1395r and 1395s. If a claim qualifies, then the insured is “entitled” to Medicare Part B payment of the claim. *See* 42 U.S.C. §§ 1395ff(a)(1)(A) (“entitled to benefits”) and 1395k(a)(1)/(2) (“entitlement to have payment made to him or on his behalf”). If the insureds (like Mrs. Smith) do not pay the premiums, they are dropped from coverage by Medicare Part B, just like Aetna or Humana would. *See* 42 U.S.C. § 1395q(b)(2) (coverage terminated for non-payment).

When an insured receives a device/service, that is called the “date of service.” Insureds have up to one year from the “date of service” to submit a claim. *See* 42 U.S.C. §§ 1395f(a), 1395n(a); 42 C.F.R. 424.44. Further, 42 U.S.C. § 1395ff(b)(1)(E)(i) specifies an amount-in-controversy requirement for judicial review. Accordingly, in many instances, it is preferable for an insured to wait to submit claims so that the total amount of submitted claims exceeds the amount in controversy requirement.

For several years, the Secretary has been engaging in bad faith conduct in denying Medicare Part B claims for continuous glucose monitor (CGM) coverage. Pursuant to the Medicare Act, Medicare Part B covers “durable medical equipment.” See 42 U.S.C. § 1395x(n). The Secretary has issued regulations further defining this term to include an item that:

- 1) Can withstand repeated use;
- 2) Has an expected life of at least 3 years;
- 3) Is primarily and customarily used to serve a medical purpose;
- 4) Generally is not useful to an individual in the absence of illness or injury; and
- 5) Is appropriate for use in the home.

See 42 C.F.R. § 414.202.

Prior to 2017, the Secretary had an unwritten policy of rejecting CGM claims on the grounds that a CGM is “precautionary” – a non-statutory/non-regulatory term. Through 2017, the undersigned counsel obtained more than 30 decisions from ALJs within HHS finding CGMs covered “durable medical equipment” despite the

unwritten policy. Mrs. Smith was one of the people who obtained a favorable decision from an ALJ finding her CGM a Medicare covered benefit. In addition, the undersigned counsel had filed three federal District Court lawsuits challenging cases where claims were denied on this ground.

On January 12, 2017, the Secretary altered his tactics by issuing a Ruling (CMS 1682-R) effective that same day. The Ruling purported to interpret the phrase “primarily and customarily used to serve a medical purpose” and labelled all but one CGM at the time “non-therapeutic” and not “primarily and customarily used to serve a medical purpose.” As a result, these CGMs were also labeled not “durable medical equipment” and were excluded from coverage.

Subsequently, the judges in the cases filed before January 12, 2017, found that CGMs were “durable medical equipment” and a Medicare covered benefit.

Procedural Background

Mrs. Smith filed this case on April 5, 2021. *See* Dkt. #1. The Complaint makes a number of allegations and includes multiple causes of action. As set forth in the Complaint, Mrs. Smith alleged that the Secretary issued CMS-1682-R illegally in violation of 42 U.S.C. § 1395hh. *See* Dkt. #1, ¶¶ 28-38. In addition, Count III alleges that the denials in this case were made without observance of the procedure required by law, referencing the notice and comment allegations. *Id.* at ¶¶ 103-105. Finally, the Prayer for Relief asks the Court to set aside CMS 1682-R. *Id.* at 22. The

Prayer also asks the Court to find that CGMs are “durable medical equipment” within the meaning of the appropriate statute and regulations. *Id.*

Thereafter, the Secretary filed a “Response”, which did not respond to the allegations of the Complaint. *See* Dkt. #10. Instead, the “Response” offered that one of the three claims at issue should have been covered under some unidentified rationale. As to the second and third claims, the Secretary requested that they be remanded so that the Secretary could consider different grounds to reject them. *Id.* Thereafter, this Court ordered the Secretary to file an Answer compliant with the Federal Rules.

On August 24, 2021, the Secretary filed an “Answer” that Plaintiff contends was filed in violation of FED.R.CIV.P. 11 and, in addition to the bad faith denials of the allegations of the Complaint, was filed for the improper purpose of concealing the Secretary’s positions until after Mrs. Smith filed motions for summary judgment. *See* Dkt. #24. Mrs. Smith sought relief from the schedule so that the propriety of the “Answer” could be addressed before summary judgment briefing. *See* Dkt. #25. This Court did not respond.

Thus, consistent with the Scheduling Order, Mrs. Smith filed motions for summary judgment on September 7, 2021. *See* Dkt. #28 and 29. The improper purpose achieved, the Secretary promptly filed a new “Answer.” *See* Dkt. #30.²

In violation of DUCivR 7-1(a)(3), on September 21, 2021, the Secretary filed two copies of a combined opposition to Mrs. Smith’s two motions for summary judgment as well as cross-motion on the same. *See* Dkt. #s 31 and 32.

On December 28, 2021, the Secretary published a notice of proposed final rule making with regard to CGM coverage. Importantly, the proposed rule is only effective for claims with dates of service after February 28, 2022, and does not apply to claims with dates of service before that date. Illustrative of this fact is that Mrs. Smith has another pending claim rejected on the basis of the illegally issued CMS 1682-R and that rejection has not been withdrawn. *See* Exhibit A.

On January 5, 2022, Mrs. Smith filed a motion for a status conference and/or a ruling on the pending motions. *See* Dkt. #50. On January 7, 2022, the Secretary filed a response wherein the Secretary requested that the Court simply enter judgment on the three claims, without addressing the illegality of CMS 1682-R. *See* Dkt. #51. That approach would allow the Secretary to continue to engage in illegal

² The new “Answer” amended the particular responses that were the subject of the motion for summary judgment but otherwise repeated numerous bad faith denials (*e.g.*, jurisdiction, venue).

conduct – even as to Mrs. Smith, while avoiding judicial review and/or subjecting Mrs. Smith to repeated litigation that collateral estoppel exists to avoid.

Finally, on January 19, 2021, this Court issued a docket text order stating: “In light of the Secretary's renewed confession of error and his ‘request to enter judgment in favor of plaintiff and to remand to the Secretary to pay the claims at issue in this case,’ Dkt. No. 51 at 2, this matter will be remanded to the Secretary with directions to pay Plaintiff's three claims. 28 Motion for Summary Judgment, 29 Motion for Summary Judgment, 31 Cross Motion for Summary Judgment, and 49 Motion for Status Conference or Ruling on Pending Motions for Summary Judgment are DENIED AS MOOT.”

Legal Background

Under FED.R.CIV.P. 59(a)(2), after a non-jury trial, the Court may open the judgment to amend findings of fact and conclusions of law or make new ones, and direct the entry of a new judgment. Action is warranted under pursuant to FED.R.CIV.P. 59(e) when there is: 1) an intervening change in the controlling law; 2) new evidence previously unavailable; or 3) the need to correct clear error or prevent manifest injustice. *See Servants of the Paracletes v. John Does*, 204 F.3d 1005, 1012 (10th Cir. 2000).

It is elemental that a suit is moot “only when it is impossible for a court to grant any effectual relief whatever to the prevailing party.” *See Knox v. S.E.I.U.*

Local 1000, 567 U.S. 298, 307 (2012) (cleaned up). When assessing mootness, it is elemental that a Court should consider whether a favorable decision would have some effect in the real world. *See, e.g., E.E.O.C. v. CollegeAmerica Denver*, 869 F.3d 1171, 1173-74 (10th Cir. 2017). Further, to determine mootness, a court must first determine what the claimant seeks. *See Bais Yaakov of Spring Valley v. ACT, Inc.*, 798 F.3d 46, 53 (1st Cir. 2015).

When a defendant voluntarily stops challenged conduct, the claim is deemed moot only if: 1) it is absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur; and 2) interim relief or events have completely and irrevocably eradicated the effects of the alleged violation. *CollegeAmerica*, 869 F.3d at 1173-74.

DISCUSSION

Mrs. Smith is unable to determine under what authority/procedure the Court's docket text order of January 19, 2022 was entered. No relevant motion under FED.R.CIV.P. 12 or 56 was pending and, as detailed above, the Secretary's "pleading" (*i.e.*, the Answer) denies the allegations of the Complaint). No matter how construed, the procedures of the Rules are designed to avoid this very situation – without notice - claims and causes of action are dismissed/not addressed. Respectfully, judgment entered on January 19, 2021, and the failure to address the

causes of action and actual relief sought is “clear error”/”manifest error” and the judgment should be withdrawn.

As detailed above, Mrs. Smith has a cause of action seeking a determination that CMS 1682-R issued illegally and setting it aside. The payment of the particular claims at issue does not render that cause of action/request for relief moot. In addition, as detailed above, the Complaint in this case seeks a number of findings that will have real world impact on Mrs. Smith. For example, a finding that Mrs. Smith’s CGM is “durable medical equipment” will estoppel the Secretary from denying that in the future.

Likewise, a ruling on collateral estoppel would have real world effect. In particular, as detailed above, Mrs. Smith has pending claims that are being denied on the bad faith, illegal policy. Incongruously, the Secretary’s January 7, 2022, filing includes a suggestion on how Mrs. Smith can appeal the bad faith, illegal denial of her claim. *See* Dkt. #51 at 4 (“If so, she could appeal the decision on that basis to the Administrative Law Judge.”). But of course, as set forth in Mrs. Smith’s pending motion, the Secretary should be collaterally estopped from denying coverage in any event as a result of Mrs. Smith’s prior successful litigation. Thus, a ruling on collateral estoppel will have a real world effect in determining how Mrs. Smith’s instant claims, her other pending claims, and other Medicare insured’s claims are handled.

Further, rather than ceasing the offending conduct, the Secretary's December 28 publication indicates his intention to apply the bad faith, illegal policy of CMS 1682-R for another year. Moreover, as Mrs. Smith has indicated in other papers, because the illegal CMS 1682-R is a "Rule", neither ALJ nor the MAC have any discretion not to apply it and must reject CGM claims that do not comply with the bad faith, illegal policy. See 42 C.F.R. § 405.1063(b) ("rulings are binding on ... all HHS components that adjudicate matters under the jurisdiction of CMS").

Nothing is moot.

CONCLUSION

Mrs. Smith's motion should be granted. The judgment entered on January 19, 2022, should be withdrawn and the Court should address the claims and relief sought.

Dated: February 4, 2022

Respectfully submitted,

PARRISH LAW OFFICES

/s/ James C. Pistorino
James C. Pistorino
Attorneys for Plaintiffs

LEAR & LEAR PLLC

/s/ Phillip Wm. Lear
Phillip Wm. Lear
Attorneys for Plaintiff